88-1568

No.

Supreme Court, U.S.
FILED
MAR 20 1989
JOSEPH F. SPANIOL, JR.
CLERK

In the Supreme Court

OF THE

United States

OCTOBER TERM, 1988

GEOFFREY A. DI BELLA, M.D.,
Petitioner,

VS.

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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QUESTIONS PRESENTED

1. Indictment description of "approximately" destroys proper evaluation and therefore judgment must be vacated.

2. Aggregate act of prescribing is not a crime and therefore judgment must be vacated.

3. Prescribing of drugs by a doctor without wrongful intent is not a crime and therefore judgment must be vacated.

4. Failure by Courts to adequately review case requires judgment to be vacated.

5. Failure by Courts to adequately review Habeas-2255 petition requires judgment to be vacated.

LIST OF PARTIES

The parties in this case are Geoffrey A. Di Bella, M.D., and the United States of America, as shown in the caption. This Petition does not concern the other persons who were Defendants in the case.

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No.

In the Supreme Court

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MARCH TERM, 1989

GEOFFREY A. DI BELLA, M.D.,
Petitioner,

VS.

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Petitioner, Geoffrey Di Bella, M.D., respectfully prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Second Circuit, denying relief under the doctrine of Habeas Corpus and 28 U.S.C. 2255 relating to a judgment of conviction entered against him by the United States District Court for the Southern District of New York.

OPINIONS BELOW

The Denial, not officially reported, appears herein at Appendix B. The opinion of the Court of Appeals, also not officially reported, concerning the original case appears herein at Appendix E.

JURISDICTION

The Judgment of the Court of Appeals was entered on October 20, 1988 and the request for re-hearing was denied on December

21, 1988. The jurisdiction of this Court rests on 28 U.S.C. 1254(1), 28 U.S.C. 2255, and Article I, Section 9 of the Constitution.

STATUTORY PROVISIONS

The statutes involved are 21 United States Code, Sections 802, 822, and 841. Also, involved is 21 Code of Federal Regulation § 1306.04 (a). The pertinent parts of the statutes and Regulation are set forth in the appendix, part C.

STATEMENT OF THE CASE

Introduction

There was a revolution and this country was founded because certain principles were considered so basic, so fundamental, so essential that they had to be part of a civilized society. Those principles all involve justice. Some like Due Process, Habeas Corpus, Trial by Jury are specifically set forth in the Constitution and others are so intertwined with a fair application of those concepts—like instructing the jury properly, following the legal procedures that are required, having a meaningful attorney-client relationship, having an appeal that truly evaluates the trial's fairness—that they necessarily must be considered a part of Constitutional Rights. In our twentieth century American society is this all to be forgotten? Superficial judgments are being made, and apparently the Courts now are more concerned about "moving cases", thereby counting numbers to justify their existence, instead of assuring that justice is done in each case. In addition there seems to be a hysteria about anything that involves "drugs" so that careful evaluation is no longer deemed appropriate. Unfortunately, this superficiality has struck this case—it hasn't been properly handled—and now it is imperative that the Court act to rectify the matter.

Perhaps part of the reason for the Courts failure to act properly was that this case doesn't fall under the categories of gimmicks or of sensationalism. Perhaps the lower Courts would have been more concerned about the many errors that occurred if that had been the case. So, no—this is not about a grisly murderer, a mafia

chieftain, or a crazed sex assaulter. There has been no movie made that is pressuring the Court to do what it should have done in the first place. Newspaper headlines and articles have not been written urging the Court what to do. But that doesn't mean this case is not important. It is important. Obviously, it is important to the Appellant because a great injustice has been done to him. It is important because it indicates the Courts are not working properly and therefore they need to be directed to get back on the proper course. It is important because the law deals with the practice of medicine and there is great conflict in the interpretation of the laws applicable to this kind of case. There are over 500,000 doctors in the United States—this case effects every one of them.

The Charge and the Results

In December 1984 Dr. Di Bella was indicted for conspiracy to distribute and two substantive counts of distribution of methaqualone ("quaaludes") a "Schedule II" controlled substance. The indictment, which named eight defendants in various combination of counts, concerned the activities of an organization called Jorum, which the government alleged served as fronts for the distribution of quaaludes. Dr. Di Bella was one of five physicians named in the indictment, each of whom worked for various periods at the clinical facilities run by Jorum in the City of New York. Following a jury trial, Dr. Di Bella was acquitted of conspiracy, but convicted of the distribution counts.

He was sentenced to concurrent sentences of two years imprisonment, to be followed by two years of special parole, and a $5,000.00 fine. He presently is on the special parole.

Potentially Negative Aspects of the Case

An understanding of some of the alleged indicators of illicit conduct will assist in an understanding of this case and, will further indicate why the overturning of this case is mandated. A potential damaging inference may arise from the fact it involves a controlled substance drug. That would not be a fair inference. This arrangement with Jorum was considered a specialized prac-

tice for treating insomnia wherein the treatment mode was a drug, and the drug of choice was quaalude (methaqualone). At the time Methaqualone was a schedule II controlled substance drug. However, this merely means theoretically it has a high potential for abuse. It wasn't and isn't clear if "abuse" meant in a recreational sense or in a dangerous sense, like addictive or life threatening. That wasn't brought out clearly in trial, though it seemed there was an attempt at one time to portray the drug as dangerous. Likewise it wasn't brought out in trial if it was, in fact, considered dangerous by the medical community. Further, no patient was brought out to show that patent had been harmed. Regardless, the drug very clearly at the time was considered appropriate for insomnia, and there was little testimony that the drug, in relation to some other drug, was not appropriate for the patients who were seen at the Jorum facility. Indeed, no one contradicted Dr. Di Bella's testimony that it was an excellent drug for the treatment of insomnia.

Another factor that was suppposed to infer a knowledge of wrongfulness was the amount paid to the Doctors. To be sure the fee paid by the patient, $150.00 to $200.00, was high but the bulk of the money went to Jorum. When analyzed about who got the most money this seems to re-enforce the view that Dr. Di Bella was naive about the nature of the patients, and was as much a victim as anyone else.

Indeed, a careful review of the facts will point to only one conclusion. Dr. Di Bella was a very naive doctor, and inexperienced about operating a medical practice, and because of these factors unknowingly became a participant in a sham medical operation. The fact that the prosecution was unable to bring forth a witness to say that Dr. Di Bella ever behaved as if this was a sham is only one of many aspects of the evidence which suppports this interpretation. Unfortunately, detailed background of Dr. Di Bella was not provided at trial nor did he give, at trial, an explanation of his impressions when he testified because he was under the mistaken belief he was to be as detached and unemotional as the situation allowed. Nevertheless, a review of the psychological reports done after trial, which are part of the Reply Brief in case no. 86-1224 (Second Circuit) and the Reply Brief in

case no. 88-2225 (Second Circuit) confirm and make it overwhelmingly clear that Dr. Di Bella had no wrongful intent at the time he wrote the prescriptions which are the subject of this case.

Inappropriate Evaluations

No one is asking that you believe Dr. Di Bella at this point in time. All that is being asked is that the Courts follow the law. Despite repeated requests this hasn't happened. Accordingly it is necessary to explain some of the issues which have been raised and the Courts failure to adequately judge them. To begin with the trial was not a fairly conducted forum attempting to ascertain the truth. For example, the Judge made no effort to control the testimony of the expert witnesses and therefore their testimony improperly used legal language which at the least confused the jury, and, in any event, usurped their function. Numerous exhibits and compilation of exhibits were allowed into evidence without proper foundation. Two points deserve particular emphasis and therefore need to be brought out for the purposes of this Brief. One, and a major problem that compounded the unfairness of this trial, was that Dr. Di Bella didn't explain his point of view in personal terms concerning why he acted as he did. Second, the instructions to the Jury were wrong. Arguably, they were very close to being correct, but since so much of this case depended on an analysis of Dr. Di Bella's mental state, to imply to the jury that an analysis of Dr. Di Bella's mental state was not necessary—because an objective standard of evaluation applied to the situation—plainly was error. In other words, the fact of the matter was that the law as explained to the jury was not and is not the law!

Court of Appeals Failures

The failure to follow the law is even more frightening in the Court of Appeals. It was and is absolutely extraordinary that the Courts make the superficial analysis that they have and think of Dr. Di Bella as such a simple-minded person. It is not surprising that in their cursory opinion they don't get the facts right.

An examination of the Appeals Court opinion, Appendix E, shows this to be the case. They mention Dr. Di Bella, but make no distinction between him and the other doctors. Everyone agrees this was not the case. Everyone agrees that the Doctors worked at Jorum at different times. Further, the Doctors followed different procedures and spent differen amount of times with the patients. For example, Dr. Di Bella was the only one who introduced hand-outs advising of the proper use of methaqualone. The Court also mentions one doctor, Dr. Gourji, as if to say he realized his guilt subsequent to trial and therefore didn't waste everyone's time with an appeal. That was completely wrong. It again shows the lack of real examination of the case. That doctor simply had not been sentenced by the time of the appeal and therefore couldn't appeal. (Entry of judgment must take place before an appeal may be submitted). And that doctor, later did, in fact, appeal. If they can't get the facts correct then it isn't any wonder that they didn't get the law correct. No other jurisdiction agrees with the Second Circuit in their lack of requirement of a mental state. No other jurisdiction says that a doctor's mental state is not a necessary component in a guilty finding in relation to the illegal prescribing of drugs.

Habeas Corpus "2255" Procedure Didn't Rectify Errors

The issues were properly raised before the trial Court in a motion after the Verdict, again raised in the Court of Appeals, again raised in a Writ before the Supreme Court, again raised in a Request for a Writ of Habeas Corpus before the Trial Court ("2255 motion"), and again raised with the Court of Appeals. The lack of consideration given to these issues is, by itself, a fundamental denial of due process.

The improper interpretation of the law is not just a remote instance. It happens throughout the case. Accordingly, even though Appellant again has raised all the issues in the 2255-Habeas Corpus procedure—and in addition raised the illegality of the procedure, and the ineffectiveness of counsel—the trial Court and the Circuit Court for the Second Circuit Appellate Division have not been willing to fully and properly answer the issues.

Instead, for the most part, they answer by simply denying. Thus, for example it isn't surprising that the trial Court in responding to the 2255 Petition (Appendix A) exaggerates the guilt indicating factors, shows the Court's misunderstanding of the reference to psychological principles, and totally misstates the defense contention on entrapment (which contrary to what was stated by the court, had nothing to do with prosecuting similar violators).

They don't have the right to blame the briefing. It is submitted the briefs in this case were excellently written, and the facts were accurately reported by the Appellant in his trial court briefs, and in his opening and reply appeal briefs. It is submitted that the Government briefs were not as well written, and didn't as fully bring the issues in focus, but were not poor either. Thus what has happened in this case is not proper. And it shouldn't be legal. Now this Court must act to change the situation. This "cover-up" is no more tolerable in the Judicial Branch than it is in the Executive Branch, and it's directly opposite to our values of Government.

The illegalities of this case are by themselves sufficient for this Petition to be granted and, without further pleadings, the Judgment vacated and the Writ issued. As stated earlier, while Dr. Di Bella maintains his innocence, it isn't necessary for the Court to believe his version for the judgment to be found void and therefore vacated.

LEGAL REASONS FOR THE SUPREME COURT TO VACATE JUDGMENT AND IMMEDIATELY GRANT WRIT OF HABEAS CORPUS

A PERSON MAY NOT BE APPROXIMATELY GUILTY

First, in America a person may not be "approximately" guilty of a crime. Over objection, the indictment was given to the Jury in this case and the language of the indictment was that an approximate number of prescriptions had been written (Appendix D). That is plain, severe, reversible error. There is no such law. Nothing more should need to be said: the responsibility of the jury before it is allowed to enter a conviction is to be convinced with definiteness and certainty that each of the issues has been proven beyond a reasonable doubt. NOT APPROXIMATELY.

WRITING OF PRESCRIPTIONS IN THE AGGREGATE IS NOT A CRIME

The second illegality is that there is no such crime as defined by the Second Circuit to the jury. The indictment charged a group of prescriptions had been written. While if this had merely appeared in the indictment it might not have been a flaw. However, the indictment was given to the jury and it never was explained to the jury that each prescription must be evaluated. Accordingly, any determination cannot be valid because one can't be guilty of prescribing a group of prescriptions; one only may be guilty of wrongfully writing one prescription. *United States v. Kirk*, 584 F.2d 773 (6th Cir. 1978). This is not sophistry. While one may have been convicted of many wrongful prescriptions and therefore guilty of prescribing a group of prescriptions, to merely allege the group takes away the necessity of each individual situation being analyzed. And, while it may appear to be intellectualizing, the criminal law is read narrowly, and, in fact, there is no crime for writing an aggregate number of prescriptions. While a finding on the group strongly suggests the individual prescription was incorrect it doesn't necessarily follow that such was the case.

Also, it deserves mention that because the word "approximately" was used the jury in actuality didn't even determine a definite group of prescriptions had been wrongfully written.

OFFENSE AS DEFINED BY THE SECOND CIRCUIT IS NOT A CRIME

The criminal offense of illegal distribution of drugs means that the person had the intent to commit a wrongful act and, in such a frame of mind, delivered a drug to another person. The second circuit makes the argument that in relation to doctors, the state of mind is irrelevant. *U.S. v. Vamos*, (1986) 797 F.2d 1146, *U.S. v. Sanchez-Acosta* (this case; the unpublished opinion is in the appendix). There is no such law as claimed by the Second Circuit. No other circuit agrees with them. Because of this conflict in the Circuits and the fundamental importance of this issue, as it directly effects hundreds of thousands of doctors who in turn are treating with drugs the population of the United States, now believed to be about 250 million people, the Court needs to review the matter. Further, an additional reason for

review is that the Supreme Court's decision in *U.S. v. Moore,* (1975) 423 U.S. 122, 96 S.Ct. 335, 46 L.Ed. 333, is not being interpreted correctly and therefore needs to be clarified.

This was used by the Second Circuit to say that what the experts said at trial didn't matter. Also, it appears to rationalize jury instructions which lacked an intent requirement in relation to the law on distribution and conscious avoidance. That isn't the law, however. Quite the contrary—it is presumed Congress requires unlawful intent of a felony crime unless Congress explicitly states otherwise. *Liparota v. Unites States,* (1985) 471 U.S. 419, 85 L.Ed. 434, 105 S.Ct. 2084. Thus, once again this judgment is void and therefore must be vacated.

SECOND CIRCUIT COURT OF APPEALS DIDN'T FOLLOW CORRECT LAW OF REVIEW AND THEREFORE THE CASE MUST BE REVERSED

In addition to the obvious glossing over of the facts which was addressed earlier in this pleading there are other errors by the Second Circuit. It also is obvious that no attempt was made to understand the actions of Dr. Di Bella. The Court of Appeals automatically assumed that methaqualone (quaalude) must be a bad drug because it was a scheduled drug and therefore everything else was an obvious criminal venture. It is submitted that while doctors are not or may not be as careful about controlled drugs as is a lawyer's impression that they should be, most of them, unlike lawyers and judges are not thinking in a framework of "cops and robbers", but are thinking they are treating genuine patients. Similarly, just because a drug is on a schedule, it is submitted, that doctors would not assume there was something wrong with it. In fact, practically all the sleeping pills and tranquilizers are somewhere on the controlled substance schedules, from I to V, and they are subject to being moved from one schedule to another. While those facts may not have been brought out clearly at trial, nevertheless the Court of Appeals was expected and required to evaluate the case according to law and not jump to conclusions.

The Appeals Court relies on the assertion that all reasonable inferences, and all issues of credibility must be resolved in favor of the Government. However, that omits a very important rule

which must be applied to this case. Here, on a related charge arising from the same set of facts, Dr. Di Bella was acquitted of a conspiracy. Arguably, this means that the underlying, substantive charges—the distribution counts—ought to be vacated. In fact, this is particularly true in light of how the substantive charges are phrased so that it is a group of prescriptions rather than an individual act. At the very least, the law requires the rule that when an inconsistency appears in the verdict a reviewing court "should be extraordinarily careful to scrutinize the record for the ascertainment of any prejudicial error". *Manley v. United States*, 238 F.2d 221 (1956). That wasn't done and therefore the case must be reviewed in accord with the Supreme Court's supervisory capacity.

This failure to make a meaningful analysis is confirmed by a quick reading of the Reply Brief by Dr. Di Bella and the Court's opinion—many issues simply were left unanswered. For example:

1. statistical evidence, such as proof by percentages, should not have been allowed to serve as "the" proof;

2. a standard of conduct which is within the scope of medical practice (a means of comparison) was not established by Expert witnesses.

3. the conscious avoidance instruction was improper to give and also incorrectly given.

4. the aiding and abetting instruction was improper to give.

SECOND CIRCUIT COURT OF APPEALS DIDN'T SUFFICIENTLY REVIEW SECTION 2255-HABEAS CORPUS BRIEF

Similar to their lack of analysis of the Appellant's original appeal, the Court of Appeals for the Second Circuit failed to adequately review the challenge to the legality of the proceedings filed by the Appellant on his own behalf. This was his brief authorized by the principles of Habeas Corpus and 28 U.S.C. 2255.

This was a thorough analysis of ineffective assistance of counsel. Even though he was criticizing this writer, this writer must admit it states a prima facie case and there should have been a

hearing ordered on the matter, as is required by 22 U.S.C. 2255. One of the major points that was made was that a proper investigation was not made into a mental defense. This is required by the Fifth Circuit, *Beavers v. Belkcam,* (1981) 636 F.2d 114 and thus a conflict exists with the Second Circuit.

A second point was that he did not know that a potential entrapment defense may have been available and he should have been informed of that. The Second Circuit's failure to act puts it in direct conflict with the Fifth Circuit. *United States v. Greenfield*, 554 F.2d 179, 54 A.L.R. Fed. 632.

Undoubtedly, the effect of the cumulative errors of this case even if a single one may not be sufficient is cause for reversal of this case.

CONCLUSION

Wherefore, it is requested that a Petition for Certiorari issue so that the actions of the lower courts may be reviewed, the illegal judgment be vacated, and the Appellant Geoffrey Di Bella be released from control of the United States, and for such other and further relief as the Court may find appropriate.

Respectfully submitted,

NICOLAS M. W. DI BELLA

March, 1989

Appendix A

United States District Court
Southern District of New York

Geoffrey A. W. Di Bella, M.D., et al.
(including G. A. W. Di Bella,
Petitioner,

against

United States of America,
Respondent.

87 Civ. 8764 (GLG)
ORDER

The petitioner moves to vacate his conviction in 1985 of two counts of unlawful distribution of methaqualone in violation of Title 21 U.S.C. §§ 812 and 841. Following the conviction, he appealed unsuccessfully. He thereafter commenced serving a two-year term of imprisonment which he continues to serve.

The petitioner alleges that there was a "complete miscarriage of justice" in his conviction. He was one of a number of defendants, including a handful of doctors charged with running "quaalude" clinics. In addition to being a licensed medical doctor, he was also a qualified psychiatrist. The evidence at trial clearly established, with respect to the petitioner, that he wrote 771 prescriptions for quaaludes in 27 working days and as many as 96 in a single day. Patients would come in to see him, spend five minutes, pay $200.00 in cash, and he would then present them with their desired prescription for the controlled substance. He turned away only one patient in 100. The rest paid their money and got their drugs.

In arguing that his conviction was a miscarriage of justice, he contends that his attorney (his brother) prevented him from or failed to establish that because of his emotions and personality he could not have had a criminal intent. As he describes it in his petition, "my immaturities involved the medical diseases of Bulemia and Avoidant and Compulsive Personality Disorders. Part of the manifestation of these diseases include a severe

naivete, literal-kindedness, severe interpersonal awkwardness, and poor ability to judge many aspects of reality."

One of the goals of psychiatry is to have patients confront the consequences of their own actions. This doctor-psychiatrist has been unable to do that. While he and the other doctors attempted to argue to the jury that they thought these drug users were legitimate patients in need of prescriptions, and that they saw nothing unusual in having so many patients with the same illness in need of the same drug, the jury quickly disposed of that contention. The fact that the "patients" laid out over $150,000.00 for petitioner's prescriptions in a period of 27 days clearly gave the transactions a commercial overtone.

This petitioner, who still refers to himself as doctor (apparently his license to practice medicine has not been revoked), not only violated the law but made a mockery of the Hippocratic oath in his sworn duty not to do harm to his patients. That his time in jail has not led to an acceptance of his responsibility is indeed sad. The conditions of which he claims to have suffered during his period of criminal activity would not, under any circumstances, be a defense to the charges against him in light of the overwhelming proof.

The petitioner raises a number of other issues which, as noted in this court's order of December 16, 1987, were either frivolous, raised on appeal or waived by failure to raise them. In addition, there is another issue which was decided on the appeal of a co-defendant (severance). We have considered all of the grounds urged by the petitioner, including the frivolous claim that he was entrapped into illegal activity by the failure of the Government to prosecute similar violators, and dismiss his petition as being meritless.

SO ORDERED.

Dated: White Plains, N.Y.
April 4, 1988

GERARD L. GOETTEL
Gerard L. Goettel
U.S.D.J.

Appendix B

United States Court of Appeals
for the
Second Circuit

At a stated term of the United States Court of Appeals for the Second Circuit, held at the United States Courthouse, in the City of New York, on the twenty-first day of December, one thousand nine hundred and eighty-eight.

Docket Number 88-2225

Geoffrey A.W. Di Bella, M.D.
(including G.A.W. Di Bella),
Plaintiff-Appellant,

v

United States of America,
Defendant-Appellee.

[Filed Dec. 21, 1988]

A petition for rehearing containing a suggestion that the action be reheard in banc having been filed herein by Appellant Di Bella

Upon consideration by the panel that heard the appeal, it is

Ordered that said petition for rehearing is DENIED.

It is further noted that the suggestion for rehearing in banc has been transmitted to the judges of the court in regular active service and to any other judge that heard the appeal and that no such judge has requested that a vote be taken thereon.

ELAINE B. GOLDSMITH
Clerk

by /s/ Fred Cassidy
Deputy Clerk

United States Court of Appeals
for the Second Circuit

At a stated Term of the United States Court of Appeals for the Second Circuit, held at the United States Courthouse in the City of New York, on the 20th day of October, one thousand nine hundred and eighty-eight.

Present: Honorable Ellsworth A. Van Graafeiland, Honorable Richard J. Cardamone, Honorable Lawrence W. Pierce, Circuit Judges.

Geoffrey A. W. Di Bella, M.D.
(including G.A.W. Di Bella),
Plaintiff-Appellant,

against

United States of America,
Defendant-Appellee.

ORDER
Docket No. 88-2225

[Filed Oct. 20, 1988]

Geoffrey Di Bella, *pro se*, appeals from an order entered on April 4, 1988 in the United States District Court for the Southern District of New York (Goettel, J.), which denied his habeas corpus petition filed pursuant to 28 U.S.C. § 2255.

On March 14, 1985 appellant was charged with conspiracy to distribute a controlled substance outside the scope of professional medical practice, in violation of 21 U.S.C. § 846, and with the unlawful distribution of a controlled substance (methaqualone, sold under the trade name "Quaalude"), in violation of 21 U.S.C. § 841(a)(1). Following a jury trial, he was found guilty in violation of the unlawful distribution charge, but was acquitted of distributing outside the scope of medical practice. We affirmed the conviction, *United States v. Di Bella*, Dkt. No. 86-1224 (2d

Cir. Nov. 19, 1986), *cert. denied*, 107 S. Ct. 3184 (1987), and his petition for a writ of certiorari was denied on June 8, 1987. *Di Bella v. United States*, 107 S. Ct. 3184 (1987). Throughout all these proceedings, Di Bella was represented by counsel.

The principal thrust of appellant's petition is that his conviction was a "complete miscarriage of justice" because his attorney failed to establish that his emotions and personality were inconsistent with criminal intent, and that his trial should have been severed from that of his co-defendants.

Dec. 29, 1988
Issued as mandate:

We affirm the denial of the habeas petition for the reasons states in Judge Goettel's careful opinion dated April 4, 1988.

The order of the district court is affirmed.

/s/ ELLSWORTH A. VAN GRAAFEILAND
Ellsworth A. Van Graafeiland, U.S.C.J.
/s/ RICHARD J. CARDAMONE
Richard J. Cardamone, U.S.C.J.
/s/ LAWRENCE W. PIERCE
Lawrence W. Pierce, U.S.C.J.

Appendix C

The pertinent part of 21 U.S.C. 841 is:

(a) Except as authorized by this subchapter, it shall be unlawful for any person to knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance;

The pertinent part of 21 U.S.C. 822:

(b) Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances are authorized to possess, manufacture, distribute, or dispense such substances (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

The pertinent parts of 21 U.S.C. 802 are:

(8) the terms "deliver" or "delivery" mean the actual, constructive, or attempted transfer of a controlled substance, whether or not there exists an agency relationship.

(10) the term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance. The term "distributor" means a person who so delivers a controlled substance.

(20) The term, "practitioner" mean a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital or other person . . . permitted, by the United States . . . to distribute, dispense, conduct research with respect to, administer, or use in teaching or

chemical analysis, a controlled substance in the course of professional practice or research.

(21) The term "ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.

Appendix D

COUNT EIGHT

The Grand Jury further charges:

Between on or about November 10, 1981, and on or about February 18, 1982, at the 34th Street Clinic in the Southern District of New York, DR. GEOFFREY Di BELLA, the defendant, unlawfully, intentionally and knowingly did cause to be distributed and dispensed, outside the scope of professional medical practice, approximately 33,240 dosage units of Quaalude (Methaqualone), a Schedule II (now a Schedule I) controlled drug substance.

(Title 21, United States Code, Section 812, 841(a)(1), 841(b)(1)(B) prior to amendment on October 12, 1984, by Public Law Number 98-473, Title 11, Section 502; Title 18, United States Code, Section 2).

COUNT NINE

The Grand Jury further charges:

Between on or about March 1, 1982, and on or about June 30, 1982, at 60 East 42nd Street, New York, New York in the Southern District of New York, DR. GEOFFREY Di BELLA, the defendant, unlawfully, intentionally and knowingly did cause to be distributed and dispensed, outside the scope of professional medical practice, approximately 5812 dosage units of Quaalude (Methaqualone), a Schedule II (later a Schedule I) controlled drug substance.

(Title 21, United States Code, Section 812, 841(a)(1), 841(b)(1)(B) prior to amendment on October 12, 1984, by Public Law Number 98-473, Title 11, Section 502; Title 18, United States Code, Section 2).

Appendix E

United States Court of Appeals
for the Second Circuit

At a stated term of the United States Court of Appeals for the Second Circuit, held in the United States Courthouse in the City of New York on the 19th day of November, one thousand nine hundred and eighty-six.

Present:

Hon. Ellsworth A. Van Graafeiland,
Hon. Lawrence W. Pierce, *Circuit Judges,*
Hon. Morris E. Lasker, *District Judge.**

86-1224, 86-1303, 86-1342

United States of America,
Appellee,

vs.

Dr. Manuel Sanchez-Acosta, Dr. Geoffrey Di Bella,
and Dr. Irving Greenfarb,
Defendants-Appellants

ORDER

[Filed Nov. 19, 1986]

Appeal from judgments of conviction in the United States District Court for the Southern District of New York (Goettel, J.). Appellants Sanchez-Acosta, Di Bella, and Greenfarb were convicted of the illegal distribution of methaqualone (more commonly known by its trade name, "Quaalude") in violation of 21 U.S.C. §§ 812, 841(a)(1) & 841(b)(1)(B). Appellant Greenfarb was also convicted of conspiring to violate federal narcotics laws under 21 U.S.C. § 846.

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* Hon. Morris E. Lasker, Senior Judge, United States District Court for the Southern District of New York, sitting by designation.

1. Appellants allege that there was insufficient evidence to establish that they were dispensing medication in bad faith. Appellants contend that in their best judgment they believed that their patients were suffering from sleep disorders and that Quaalude was the proper remedial medication. Appellants also allege that they were practicing in good faith because they were advised by competent counsel that their activities were legitimate.

When reviewing the sufficiency of the evidence, we must draw all reasonable inferences, and resolve all issues of credibility in favor of the Government. Glasser v. United States, 315 U.S. 60, 80 (1942); United States v. Martino, 759 F.2d 998, 1002 (2d Cir. 1985). The totality of the evidence adduced at trial clearly supports the jury's verdicts of guilt in this case. Each of the defendants wrote Quaalude prescriptions for more than 95% of their patients; patient examinations were very brief (usually lasting only five minutes), while the fees were quite high ($150 to $200 per visit); and further, expert testimony indicated that the medical operation was a sham. The evidence was therefore sufficient to support the verdicts.

2. Apropos appellants' argument that the prosecutor's misconduct deprived them of a fair trial, a criminal conviction will not be overturned on review unless the prosecutor's misconduct caused substantial prejudice to the defendants in the case. United States v. Biasucci, 786 F.2d 504, 514 (2d Cir.) (citations omitted), *cert. denied*, 107 S. Ct. 104 (1986). Here, appellants basically rely on two incidents to support their claim of prosecutorial misconduct. One, an altercation between the prosecutor and defense counsel, occurred outside the presence of the jury and therefore could not have resulted in prejudice. The second involved a remark before the jury, made on the first day of the month-long trial, which could be interpreted as inferring that defendant Gourji's attorney could be indicted. (Gourji did not appeal.) The prosecutor said: "You are not a defendant yet, sir." The district court immediately struck the remark from the record and chastised the prosecutor, the prosecutor apologized twice for the comment, and thereafter the district court cautioned the jury to disregard the remark. These actions eliminated any substantial

prejudice to the defendants. See United States v. Bagaric, 706 F.2d 42, 58 (2d Cir.), *cert. denied*, 464 U.S. 840 (1983).

Although we find that the prosecutor's actions did not result in substantial prejudice to appellants so as to deprive them of a fair trial, we agree that the prosecutor's outbursts and conduct were highly improper and inappropriate. Accordingly, we direct that the record herein be forwarded to the Committee on Grievances of the United States District Court for the Southern District of New York for its review of the prosecutor's conduct and for whatever action it finds to be warranted.

3. Appellants also allege that the district judge's questioning of a defense expert witness deprived them of a fair trial. Federal Rule of Evidence 614(b) specifically authorizes a trial court to "interrogate a witness, whether called by itself or a party." Indeed, a trial judge has the responsibility to assist the jury in determining the truth. United States v. Bronston, 658 F.2d 920, 930 (2d Cir. 1981), *cert. denied*, 456 U.S. 915 (1982). A conviction should be reversed only when the trial judge's conduct was so partial to the prosecution that it became a factor in determining the defendant's guilt. United States v. Pisani, 773 F.2d 397, 402 (2d Cir. 1985) (citations omitted). In this case, Judge Goettel questioned the expert witnesses of the Government as well as those of the defense. The record indicates that the trial court's questions were designed to amplify and clarify the statements of the experts. While Judge Goettel may have expressed doubt as to the defense expert's testimony in the presence of the attorneys, no such opinion was expressed before the jury. Finally, the district court instructed the jury that it should not assume that the court had an opinion about the case merely because it asked questions. Thus, we hold that the appellants were not denied a fair trial.

4. Finally, appellants argue that, by allowing expert witnesses to express an opinion concerning whether the defendants engaged in a good faith medical practice, the district court violated Federal Rule of Evidence 704(b) because, appellants urge, such testimony would address "the mental state or condition of a defendant." However, this Court has recently made clear that "good faith medical practice" in the context of the federal narcotics laws

is determined by objective standards and does not involve a defendant's subjective state of mind. United States v. Vamos, 797 F.2d 1146, 1152-53 (2d Cir. 1986). Since the expert witnesses here merely expressed their opinion that the medical practice of defendants did not conform to reasonable good faith standards, Federal Rule of Evidence 704(b) was not violated. Even if it was, the abundance of other evidence in this case would render a violation of 704(b) harmless error.

We have considered the other contentions of the appellants and find them to be without merit. Accordingly, we affirm the judgments of conviction.

/s/ ELLSWORTH A. VAN GRAAFEILAND
Hon. Ellsworth A. Van Graafeiland

/s/ LAWRENCE W. PIERCE
Hon. Lawrence W. Pierce

/s/ MORRIS E. LASKER
Hon. Morris E. Lasker,
District Judge

N.B.: Since this statement does not constitute a formal opinion of this court and is not uniformly available to all parties, it shall not be reported, cited or otherwise used in unrelated cases before this or any other court.

Supreme Court, U.S.
FILED
APR 26 1989
JOSEPH F. SPANIOL, JR.
CLERK

NO. 88-1562

In The
Supreme Court of the United States
October Term, 1988

HOLLISTER INCORPORATED,

Petitioner,

vs.

KINGSDOWN MEDICAL CONSULTANTS, LTD.
and E.R. SQUIBB & SONS, INC.,

Respondents.

OPPOSITION TO PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR RESPONDENTS

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QUESTIONS PRESENTED

The first two issues raised by Hollister are more properly presented as:

1. Whether the Court of Appeals for the Federal Circuit's reversal of the district court was proper under *Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 105 S.Ct. 1504 (1985); *United States v. United States Gypsum Co.*, 333 U.S. 364, 68 S.Ct. 525 (1948) and Rule 52(a) Fed.R.Civ.P. because on review of the entire evidence it was left with the definite and firm conviction that a mistake had been committed.

2. Whether the Court of Appeals for the Federal Circuit improperly made findings and whether it properly found that the district court had abused its discretion in finding inequitable conduct because the district court failed to consider the totality of the evidence and failed to address evidence which was necessary in order to properly draw the inferences made by the district court.

RULE 28.1 STATEMENT

Kingsdown Medical Consultants, Ltd. and E. R. Squibb & Sons, Inc. are wholly-owned subsidiaries of Squibb Corporation, a corporation of Delaware having its headquarters in Princeton, New Jersey.

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NO. 88-1562

In The
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HOLLISTER INCORPORATED,

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Respondents.

OPPOSITION TO PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR RESPONDENTS

Respondents, Kingsdown Medical Consultants, Ltd. and E.R. Squibb & Sons, Inc. (herein collectively referred to as "Squibb"), respectfully pray for denial of the petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit ("the Federal Circuit") in its Cause No. 88-1265. The judgment was entered on December 21, 1988.

OPINIONS BELOW

Kingsdown Medical Consultants, Ltd. and E. R. Squibb & Sons, Inc. v. Hollister Incorporated, 863 F.2d 867 (Fed. Cir. 1988). The opinion of the court is reproduced in Hollister's Petition at pages 1a-17a.[1]

Kingsdown Medical Consultants, Ltd. and E. R. Squibb & Sons, Inc. v. Hollister Incorporated, Case Number 84 C 6113, judgment entered January 25, 1988 as amended on February 12, 1988 in the United States District Court for the Northern District of Illinois. This opinion was not published. It is reproduced in Hollister's Petition at pages 18a-27a.

THE CONSTITUTIONAL PROVISIONS, STATUTES, RULES AND REGULATIONS INVOLVED

Patent Statutes

28 U.S.C. § 46:

Assignment of judges; panels; hearings; quorum

(a) Circuit judges shall sit on the court and its panels in such order and at such times as the court directs.

• • • •

(c) Cases and controversies shall be heard and determined by a court or panel of not more than three judges (except that the United States Court of Appeals for the Federal Circuit may sit in panels of more than three judges if its rules so provide), unless a hearing or rehearing before the court in banc is ordered by a majority of the circuit judges of the circuit who are in regular active service. A court in banc shall consist of all circuit judges in regular active service, or such number of judges as may be prescribed in accordance with section 6 of Public Law 95-486 (92 Stat. 1633), except that any

[1] Squibb will indicate references to the opinions by citations to the appendix page numbers of Hollister's Petition as "H.P."

senior circuit judge of the circuit shall be eligible to participate, at his election and upon designation and assignment pursuant to section 294(c) of this title and the rules of the circuit, as a member of an in banc court reviewing a decision of a panel of which such judge was a member.

• • • •

As amended Oct. 20, 1978, Pub.L. 95-486, § 5(a), (b), 92 Stat. 1633; Apr. 2, 1982, Pub.L. 97-164, Title I, § 103, Title II, § 205, 96 Stat. 25, 53.)

Rules of Practice of the Patent and Trademark Office

37 C.F.R. § 1.60:

Continuation or divisional application for invention disclosed in a prior application.

(a) A continuation or divisional application (filed under the conditions specified in 35 U.S.C. 120 or 121 and § 1.78(a)), naming as inventors the same or less than all the inventors named in a prior application and which discloses and claims only subject matter disclosed in the prior application may be filed as a separate application before the patenting or abandonment of or termination of proceedings on the prior application.

(b) An applicant may omit signing of the oath or declaration in a continuation or divisional application if (1) the prior application was a complete application as set forth in § 1.51(a), (2) applicant files a true copy of the prior complete application as filed including the specification (including claims), drawings, oath or declaration showing the signature or an indication it was signed, and any amendments referred to in the oath or declaration filed to complete the prior application, and (3) the inventors named in the continuation or divisional application are the same or less than all the inventors named in the prior application. The copy of the

prior application must be accompanied by a statement that the application papers filed are a true copy of the prior application and that no amendments referred to in the oath or declaration filed to complete the prior application introduced new matter therein. Such statement must be by the applicant or applicant's attorney or agent and must be a verified statement if made by a person not registered to practice before the Patent and Trademark Office. Only amendments reducing the number of claims or adding a reference to the prior application (§ 1.78(a)) will be entered before calculating the filing fee and granting the filing date. If the continuation or divisional application is filed by less than all the inventors named in the prior application a statement must accompany the application when filed requesting deletion of the names of the person or persons who are not inventors of the invention being claimed in the continuation or divisional application.

[50 FR 8379, Mar 7. 1985]

Federal Rules of Appellate Procedure

Rule 34: Oral Argument

(a) In General; Local Rule. Oral argument shall be allowed in all cases unless pursuant to local rule a panel of three judges, after examination of the briefs and record, shall be unanimously of the opinion that oral argument is not needed. Any such rule shall provide any party with an opportunity to file a statement setting forth the reasons why oral argument should be heard. A general statement of the criteria employed in the administration of such local rule shall be published in or with the rule and such criteria shall conform substantially to the following minimum standard:

Oral Argument will be allowed unless

(1) the appeal is frivolous; or

(2) the dispositive issue or set of issues has been recently authoritatively decided; or

(3) the facts and legal arguments are adequately presented in the briefs and record and the decisional process would not be significantly aided by oral argument.

Rule 35: Determination of Causes by the Court In Banc

(a) When Hearing or Rehearing in Banc Will be Ordered. A majority of the circuit judges who are in regular active service may order that an appeal or other proceeding be heard or reheard by the court of appeals in banc. Such a hearing or rehearing is not favored and ordinarily will not be ordered except (1) when consideration by the full court is necessary to secure or maintain uniformity of its decisions, or (2) when the proceeding involves a question of exceptional importance.

• • • •

(As amended Apr. 30, 1979, eff. Aug. 1, 1979.)

STATEMENT OF THE CASE

Petitioner Hollister has applied for a writ of certiorari seeking review of a decision of the Court of Appeals for the Federal Circuit reversing a judgment of inequitable conduct in the procurement of U.S. Patent 4,460,363 ("the '363 patent"). The Federal Circuit determined that the district court's finding of inequitable conduct was clearly erroneous and an abuse of discretion.

The district court based its finding of inequitable conduct on statements made by Squibb's attorney in a preliminary amendment filed in a Rule 60[2] continuation application that two of the claims, which are now claims 9 and 24 of the patent-in-suit[3], had been allowable and allowed in the parent

[2] 37 C.F.R. § 1.60.

[3] Claim 9 of the patent-in-suit was claim 43 in the continuation application which resulted in the patent. Claim 43 of the continuation application corresponds to claim 50 of the original application on which the continuation was based.

application. However, the particular claims presented, although held by the examiner to contain allowable subject matter, had been rejected during prosecution of the parent application as indefinite under 35 U.S.C. § 112 and subsequently amended and allowed.

The district court found that Squibb's patent attorney was grossly negligent in not catching the mistake because a mere ministerial review of the language of amended claim 50 in the parent application and of claim 43 in the continuation application would have uncovered the error, and because Squibb's patent attorney had had several opportunities to make that review. The district court found evidence of an intent to deceive the United States Patent and Trademark Office ("PTO"), inferring motive to deceive because Squibb's attorney had viewed the Hollister appliance before filing the application and because amended claim 50 allegedly gave Hollister a defense to infringement that unamended claim 50 (claim 9 of the '363 patent) did not. On appeal, the Federal Circuit, applying the clearly erroneous standard, was left with the definite and firm conviction that the district court had committed a mistake. (H.P. 15a) The Federal Circuit found there was only evidence of inadvertence or mistake without intent to deceive.[4]

The Federal Circuit looked at the undisputed facts which support a finding that the district court abused its discretion. (H.P. 10a) The Federal Circuit held that the intent element of inequitable conduct cannot always be inferred from a pattern of conduct that may be described as gross negligence. (H.P. 9a) Further, the Federal Circuit found that the district court's conclusion that Squibb had motive to incorrectly label claim 50 as allowed instead of allowable was clearly erroneous because the district court

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[4] To conclude inequitable conduct occurred, findings of intent and materiality by clear and convincing evidence are required. The Federal Circuit found no need to address materiality because of its decision on intent. (H.P. 8a)

did not determine whether Squibb needed claim 9 to properly bring suit for infringement. (H.P. 14a-15a) In fact, the district court refused to decide whether other claims were infringed or whether Squibb could reasonably have believed they were. (H.P. 14a) The Federal Circuit rejected the district court's apparent use of Squibb's continuation of the suit after the inequitable conduct charge was made as a basis for intent. (H.P. 15a)

The Federal Circuit met in banc to clarify existing precedent as to what proper inferences may be made from a finding of gross negligence, and as to the standard of review of gross negligence as an equitable finding. (H.P. 16a, 17a)

The Prosecution History Of The '363 Patent Pertinent To The District Court's Clearly Erroneous Finding Of Inequitable Conduct

The language of claim 9 of the patent-in-suit was the focus of the district court's holding. It states in pertinent part:

> 9. An ostomy appliance comprising a pad or dressing having a generally circular aperture for passage of the stoma, said pad or dressing aperture encircled by a coupling member and an ostomy bag also having a generally circular aperture for passage of the stoma, said bag aperture encircled by a second coupling member...

The evidence showed that the attorney hired by Squibb to prepare the preliminary amendment mistakenly indicated in the preliminary amendment that the claim which led to claim 9 had been indicated to be "allowable" and "allowed", when in fact the specific claim of the parent application had been indicated to contain allowable subject matter but had been rejected under 35 U.S.C. § 112 for indefiniteness over the meaning of the word "encircled" as describing the positioning of the coupling around the aperture in the pad. The examiner reasoned that "encircled" could only describe a planar surface.

Claim 9 set out above was unamended claim 50 in the parent application. As discussed above, unamended claim 50 was found to contain allowable subject matter; in an amendment responsive to a rejection, independent claim 50 was amended. In particular, in the parent application Squibb's attorney deleted the language stating the "aperture encircled by" and inserted therefore "a coupling member extending outwardly from said outer pad or dressing surface and encircling the intersection of said aperture and said outer pad or dressing surface...."

Following this amendment, an advisory action on form PTOL-303, Paper No. 17, was mailed September 27, 1980, and the examiner checked box 2:

> Newly proposed or amended claims 50, 7, 8, 13-18, 52, 51, 10, 11 would be allowed if submitted in a separately filed amendment cancelling the nonallowable claims.

The examiner also checked box 3 to the following effect:

> Upon the filing of an appeal, the proposed amendment will be entered and the status of the claims in this application would be as follows: Claims 50, 7, 8, 13-18, 52, 51, 10, 11 would be allowable.

Squibb consulted with outside counsel to prepare a continuation application, instead of waiting for the appeal decision, because Hollister had entered the market with its two-piece ostomy system. In the preliminary amendment filed in the continuation, all the originally filed claims were cancelled, and newly-drafted broader claims and some claims from the parent application were renumbered and submitted.

In preparing and filing the continuation application, the outside counsel for Squibb had two versions of "claim 50" in the parent application, an unamended rejected version and an amended allowed version. As is common, counsel renumbered and transferred into the continuation all claims "previously allowed" *en masse*. Claim 43 was copied from

the rejected version of claim 50 rather than amended claim 50. This error led to the incorrect listing of claim 43 as corresponding to allowed claim 50 and to the incorporation of claim 43 as claim 9 in the patent. Squibb's in-house counsel approved the continuation application for filing and did not catch the mistake.

Proceedings In The District Court

The district court rendered its opinion and announced its decision orally from the bench. (H.P. 18a-27a)

The district court concluded that the representation that claim 43 corresponded to allowable claim 50 was material and rejected Squibb's argument that the examiner must have made an independent examination of claim 43. (H.P. 21a, 22a) The district court found the materiality element of inequitable conduct, because it concluded the allowability of claim 50 turned on the amendment overcoming the § 112 rejection in the parent application. (H.P. 25a) Squibb's knowledge of materiality was inferred from claim 50 having been deemed allowable in the parent application only after the change in claim language.

The district court found evidence of deceitful intent because of its view that Squibb was negligent in not noticing the error originally and was repeatedly negligent in not noticing the error at subsequent points in the prosecution of the patent. (H.P. 26a) The district court concluded that Squibb's acts indicated evidence of an intent to deceive the PTO. (H.P. 26a) The district court stated that the narrower language of amended claim 50 gave Hollister a possible defense that Hollister's coupling member did not encircle the insertion of the aperture in the pad surface because it is connected to the pad by a web of plastic and that Squibb's patent attorney must have perceived this defense. (H.P. 25a)

The district court expressly declined to make any finding on whether the accused device would or would not infringe any of Squibb's patent claims, but motive to deceive

the PTO was inferred because Squibb's patent attorney viewed the Hollister appliance after he had amended claim 50 and before the continuation application was filed. (H.P. 25a)

The district court rejected Squibb's argument that unamended claim 50, which became claim 43 and then claim 9 of the '363 patent, satisfied the requirements of § 112 but did not expressly or unequivocally decide that question. (H.P. 25a)

Proceedings In The Court of Appeals For The Federal Circuit

The Federal Circuit properly reversed the district court's conclusion that Squibb was guilty of inequitable conduct. (H.P. 1a-17a) The Federal Circuit, applying the clearly erroneous standard of Rule 52(a) of the Federal Rules of Civil Procedure, found that the district court abused its discretion by finding intent. Specifically, the Court of Appeals for the Federal Circuit found that in light of the undisputed facts indicating the relative ease with which the ministerial error could have occurred and remained unnoticed, there was insufficient evidence to warrant a finding of intent to deceive the PTO. (H.P. 10a)

Moreover, the Federal Circuit found that the district court's finding of evidence of actual intent was clearly erroneous. Although the district court had stated there was no evidence to support Squibb's contention that the examiner examined the claims, the Federal Circuit listed nine uncontested facts supporting such contention. (H.P. 11a)

The Federal Circuit further found the district court's opinion of inequitable conduct to be clearly erroneous because the district court improperly inferred a motive for filing unamended claim 50. (H.P. 14a) In addition, the district court's inference was also improper because it had not looked at the totality of the situation, that is, whether Squibb needed claim 9 to assert infringement because no

other claims would have been infringed. Since the district court refused to address infringement, its inference was improper. (H.P. 14a, 15a) Also, since Hollister's counsel had previously rendered an opinion that the amended version of claim 50 was subject to infringement by Hollister's device, the inference of intent was ill-founded. (H.P. 15a, n.13)

SUMMARY OF ARGUMENT

The Petition for Writ of Certiorari should be denied because the Court of Appeals for the Federal Circuit correctly applied Rule 52(a) of the Federal Rules of Civil Procedure, and the rule espoused by the Supreme Court in *Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 105 S.Ct. 1504 (1985). The Federal Circuit did not simply substitute its judgment for that of the trial court in relation to the factual finding of intent. Rather, the Federal Circuit reviewed the entire record including the uncontested facts and the totality of circumstances and was "forced to the definite and firm conviction that a mistake has been committed, amounting to an abuse of discretion." (H.P. 15a) Further, the Federal Circuit properly found that the district court improperly drew inferences because it had not addressed evidence necessary in order to properly draw the inferences it made.

The in banc ruling by the Federal Circuit did not prejudice Hollister. The in banc ruling simply clarified the existing law. Hollister argues that the Federal Circuit raised the standard of proof required to establish the defense of inequitable conduct by requiring, for the first time, more than gross negligence. In reality, the Federal Circuit merely clarified that a finding of gross negligence does not compel a finding of intent to deceive in all circumstances. (H.P. 16a) Further, Hollister cannot show any prejudice because of the numerous uncontested facts cited by the Federal Circuit, including that expert witnesses for each party testified they saw no evidence of deceptive intent. Hollister's objections to not being afforded the opportunity to brief or argue before the in

banc panel is unfounded because the Federal Circuit is not required to afford such an opportunity under applicable law. Thus, the in banc clarification of existing precedent was proper and did not deny Hollister of any rights.

ARGUMENT

I. The Federal Circuit Properly Applied Rule 52(a) And The *Anderson* Rule

The decision of the Federal Circuit is properly based upon a finding that the district court abused its discretion and that its findings were clearly erroneous under Rule 52(a) of the Federal Rules of Civil Procedure and the rule set forth in *Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 105 S.Ct. 1504 (1985). The Federal Circuit properly reviewed all the evidence including objective evidence not considered by the district court, and found that the district court's findings were clearly erroneous and an abuse of the district court's discretion. (H.P. 9a)

The Federal Circuit correctly defined inequitable conduct as conduct which resides in failure to disclose material information, or submission of false material information, with an intent to deceive, which must be proven by clear and convincing evidence. (H.P. 9a) Further, the Federal Circuit correctly stated that the findings on materiality and intent are subject to the clearly erroneous standard of Rule 52(a) of the Federal Rules of Civil Procedure, and are not to be disturbed unless the Federal Circuit has a definite and firm conviction that a mistake has been committed. (H.P. 9a) This is the standard pronounced by this Court in *Anderson*. Specifically, *Anderson* cited *United States v. United States Gypsum Co.*, 333 U.S. 364, 68 S.Ct. 525 (1948) for the definition of clearly erroneous. In *Gypsum*, this Court stated:

> A finding is "clearly erroneous" when although there is evidence to support it, the reviewing court on the *entire evidence* is left with the definite and firm conviction that a mistake has been committed. (emphasis added)

Id. at 395.

Furthermore, this Court in *Anderson* citing *Gypsum* stated the following after setting forth the general rule that deference should be given to findings of a trial judge made on credibility determinations:

> This is not to suggest that the trial judge may insulate his findings from review by denominating them credibility determinations, for factors other than demeanor and inflection go into the decision whether or not to believe a witness. Documents or objective evidence may contradict the witness' story; or the story itself may be so internally inconsistent or implausible on its face that a reasonable factfinder would not credit it. Where such factors are present, the court of appeals may well find clear error even in a finding purportedly based on a credibility determination. *See, e.g., United States v. United States Gypsum Co., supra,* 333 U.S., at 396, 68 S.Ct., at 542.

470 U.S. at 575.

The Federal Circuit's decisions have been consistent with *Anderson:*

> [A] district court's expression of the basis for its ruling *may* reflect such error of fact or law as to require reversal of the judgment when the record reflects no support for such a basis. (original emphasis)

International Medical Prosthetics v. Gore Enterprises, 787 F.2d 572, 577 (Fed. Cir. 1986).

Hollister ignores the above well-settled law and attempts to infer that the meticulous review by the Federal Circuit is evidence that it substituted its own findings for those of the district court. However, this attack upon the Federal Circuit and its review is improper. As cautioned by Justice Powell in *Anderson v. City of Bessemer City, N.C.:*

> I write separately, however, because I am concerned that one may read the Court's opinion as implying criticism of the Court of Appeals for the very fact that it engaged in a comprehensive review of the entire record of this case. Such a reading may encourage overburdened Courts of Appeals simply to apply Rule 52(a) in a conclusory fashion, rather than to undertake the type of burdensome review that may be appropriate in some cases.

470 U.S. at 581. The Federal Circuit did not substitute fact findings as Hollister claims.

II. The Federal Circuit's Finding That The District Court Abused Its Discretion Is Based Upon A Review Of The Totality Of The Evidence

The Federal Circuit, in reviewing the evidence noted undisputed facts which indicated at most carelessness, but not intent to deceive:

1) the similarity in language of the two claims (unamended 50 and amended 50); (H.P. 10a)

2) the use of the same claim number, 50, for the amended and unamended claims; (H.P. 10a)

3) the multiplicity of claims involved in the prosecution of both applications; (H.P. 10a)

4) the examiner's failure to reject claims using "encircled" in the parent application's first and second office actions, making its presence in claim 43 (of the continuation application) something less than a glaring error; (H.P. 10a)

5) the two-year interval between the rejection/amendment of claim 50 and the filing of the continuation; (H.P. 10a)

6) failure of the examiner to reject claim 43 under § 112 or to notice the differences between claim 43 and amended claim 50 during what must be presumed, absent contrary evidence, to have been an examination of the continuation; (H.P. 10a)

7) the failure of Hollister to notice the lack of correspondence between claim 43 and the amended version of claim 50 during *three years of discovery* and until after it had carefully and critically reviewed the file history 10 to 15 times with an eye toward litigation; (H.P. 10a-11a) and

8) *experts for both parties testified that they saw no evidence of deceptive intent.* (H.P. 9a)

Further, the Federal Circuit found that Hollister's argument that the examiner did not examine the claims was in error.

> Hollister argues that the district court correctly determined that the examiner failed to examine the claims in the continuation application. What the district court "determined" was that there was no *evidence* that examination occurred. No finding on whether examination occurred was made by the district court, and, of course, none may be made by us. In view, however, of certain uncontested facts: (1) the absence of direct evidence that examination did not occur; (2) the presumption of correctness that attaches to administrative action; (3) Manual of Patent Examining Procedure, section 201.07 (requiring further examination of continuation applications); (4) 35 U.S.C. § 131 (requiring examination of each application;) (5) the examiner's search notes; (6) the examiner's initialing of the prior art statement; (7) the presence of seven never-before-examined claims; (8) the examiner's "see parent" notation; and (9) the submission of numerous old and newly-cited prior art references requiring comparison

> with all the claims, we decline to presume, as part of the intent analysis in this case, a failure of the examiner to perform his duty to examine the claims of Kingsdown's continuation application. (original emphasis) (H.P. 11a-12a)

Moreover, the court in a lengthy footnote pointed to direct evidence of examination. (H.P. 12a, n.8)

Hollister in its petition asserts that Squibb showed evidence of deceitful intent by continuing to assert claim 9 in the district court instead of dedicating, disclaiming or attempting to reissue the claim. The Federal Circuit more than adequately addressed the point by stating:

> [9] The district court, in finding intent, made a passing reference to Kingsdown's continuation of its suit after Hollister charged inequitable conduct. Hollister vigorously argues before us that Kingsdown's continuing its suit while failing to disclaim or reissue is proof of bad faith. A failure to disclaim or reissue in 1987, however, would not establish that Kingsdown acted in bad faith when it filed its continuation application in 1982. Moreover, a suggestion that patentees should abandon their suits, or disclaim or reissue, in response to every charge of inequitable conduct raised by an alleged infringer would be nothing short of ridiculous. The right of patentees to resist such charges must not be chilled to extinction by fear that a failure to disclaim or reissue will be used against them as evidence that their original intent was deceitful. Nor is there in the record any basis for expecting that any such disclaimer or reissue would cause Hollister to drop its inequitable conduct defense or refrain from reliance on such remedial action as support for that defense. Kingsdown's belief in its innocence meant that a court test of the inequitable conduct charge was inevitable and appropriate. A requirement for disclaimer

> or reissue to avoid adverse inferences would merely encourage the present proliferation of inequitable conduct charges.

(H.P. 15a)

The Federal Circuit did not, in violation of *Anderson*, make de novo substitution of its conclusions regarding the evidence, but simply applied the applicable legal standard to undisputed facts. As stated in *Anderson*, documents or objective evidence may contradict a witness' story and the court of appeals "may well find clear error even in a finding purportedly based on a credibility determination." 470 U.S. at 575.

Further, the Federal Circuit correctly emphasized that Squibb had no motive to mislabel claim 50 as "allowed" instead of "allowable". Confusingly, Hollister asserts that the mislabeling or mistake was an attempt by Squibb to recapture broad claim language in order to facilitate an argument that the claim read on Hollister's accused product. Specifically, Hollister argues that Squibb included claim 43 (unamended claim 50) in its continuing application because its chances of proving infringement of claim 43 were greater than its chances would have been of proving infringement of amended claim 50, in view of Hollister's "floating flange" argument against infringement of the latter. As pointed out by the Federal Circuit, the error in such an argument is that:

> Neither the court nor Hollister tells us how Kingsdown could have known in July 1982 what Hollister's defense would be years later, when suit was filed.

(H.P. 13a)

The Federal Circuit noted that a transfer of numerous claims *en masse* from a parent to a continuing application, is a ministerial act. In particular, the Federal Circuit stated:

> As such, it is more vulnerable to errors which by definition result from inattention, and is less likely to result from the scienter involved in the

> more egregious acts of omission and commission that have been seen as reflecting the deceitful intent element of inequitable conduct in our cases.

(H.P. 14a)

Furthermore, the Federal Circuit noted:

> It is not possible to counter the "I didn't know" excuse with a "should have known" accountability approach when faced with a pure error, which by definition is done unintentionally.

(H.P. 14a, n. 11)

The Federal Circuit found that the district court incorrectly inferred intent to mislead, in part, because it improperly focused in isolation on claim 9 in total disregard of the effect of other claims. (H.P. 14a) The district court made this inference of motive stating that Squibb needed claim 9 to assert infringement against Hollister. Squibb alleged infringement of claims 2, 4, 5, and 27 in addition to claim 9. Yet, incredibly the district court refused to consider infringement of the claims. The error of the district court is clear as stated by the Federal Circuit.

> The district court expressly stated that it "did not decide the issue of infringement." Because there has been no decision on whether any of claims 2, 4, 5, and 27 are infringed by Hollister's product, or on whether Kingsdown could have reasonably believed they are, it cannot at this stage be said that Kingsdown *needed* claim 9 to properly being suit for infringement. (original emphasis)

(H.P. 14a-15a)

Therefore, the Federal Circuit concluded:

> If it [Kingsdown] did not [need claim 9 for infringement], the district court's implication of sinister motivation and the court's inference of deceptive intent from Kingsdown's acts would collapse.

(H.P. 15a)

Further, the Federal Circuit noted:

> That [the above statement] would remain true even if the district court were ultimately to determine that claim 9 is actually indefinite.

(H.P. 15a, n.14)

And in support of the conclusion it also noted that:

> One of Hollister's attorneys rendered an opinion in which the amended language of claim 50 was not seen as freeing Hollister's device of infringement.

(H.P. 15a, n.13)

As set forth above, the Federal Circuit did not simply substitute its own findings for those of the district court. It is apparent that the Federal Circuit properly viewed the totality of the evidence and the Federal Circuit was forced to the definite and firm conviction that a mistake had been committed, amounting to an abuse of discretion. Therefore, the Federal Circuit properly found that the district court's finding of deceitful intent was clearly erroneous. Thus, the finding of inequitable conduct was an abuse of discretion.

III. Hollister Misconstrues The District Court's Holding To Support Inconsistent and Erroneous Arguments

The Federal Circuit has consistently held that the court reviews judgments, not opinions or phrases in opinions. *Chore-Time Equipment, Inc. v. Cumberland Corp.*, 713 F.2d 774, 781 (Fed. Cir. 1983); *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1572 (Fed. Cir. 1986); *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 (Fed. Cir. 1985).

On the one hand, Hollister argues that the district court made a finding of actual intent. On the other hand, Hollister argues that since the district court was only required to find gross negligence to support the intent element of inequitable conduct, it failed to address actual intent. Hollister asserts it was prejudiced because gross negligence would have

sufficed under the law it says existed before the Federal Circuit's opinion in this case.

Hollister's petition contains the following assertions:

> (1) He finally concluded that tainted claim 9 found its way into the patent as the result of an actual intent to deceive....

(H.P. 12)

> (2) While the district court here had found that gross negligence *would suffice* to establish intent, the district court actually found intent, not negligence. (original emphasis)

(H.P. 13)

> (3) [T]he district court found that Squibb intented to, and did, mislead the PTO....

(H.P. 14)

> (4) The district court studied documents, evaluated the credibility of witnesses, found that Squibb had acted intentionally and ruled for Hollister on that basis.

(H.P. 14)

> (5) In view of the district court's express determination that Squibb had acted knowingly, and not inadvertently....

(H.P. 20)

> (6) Rather, the district court found extensive objective evidence of actual intent to mislead.

(H.P. 21)

In fact, the sole finding relating to intent was in the context of gross negligence.[5] Nonetheless, Hollister makes the following

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[5] The district court stated, "This aspect of the case,the inequitable conduct aspect of the case, by allowing rejected claim language to find its way through a misrepresentation to the examiner into a patent, I believe clearly constitutes, clearly and convincingly, *inequitable conduct.* I believe that there is evidence of intent to mislead, because of the, as I stated, multiple times that Mr.Davis had to correct what he testified was an error." (emphasis added) (H.P. 26a)

statements in its petition in direct contradiction to its above outlined statements to support its argument of prejudice:

> (1) *It is unfair to deny Hollister, sub silentio, an opportunity to obtain actual intent to mislead findings from the district court* in that degree of detail which the district court would have provided in his [sic] findings had he [sic] known that such findings would be tested under the more stringent standard. (emphasis added)

(H.P. 24)

> (2) Aside from the district court's specific finding of intent to mislead . . . Here, *the district judge observed that the plaintiffs were guilty of, "at the very least," gross negligence. Because the district judge believed that gross negligence alone was sufficient under the law to establish the intent element of inequitable conduct, he was not required to (and did not) make more detailed findings on the evidence that supported his findings of actual intent to mislead.* (emphasis added)

(H.P. 25-26)

Hollister's argument that it has been prejudiced by the proceedings below is without merit. The district court found gross negligence and found evidence of intent. It found evidence of intent from repeated failure to catch the error and inferred deceptive intent to file claim 9 to cover Hollister's product. The Federal Circuit did not substitute fact-findings, but assessed the propriety of the district court's inferences made from a mere segment of the totality of the facts. This, an appellate court is clearly permitted to do on review.

Hollister also seeks at this late date to focus for the first time on an alleged admission by Squibb's counsel in a pretrial brief. Hollister did not rely on this alleged admission in the proceedings before the Federal Circuit. Now, Hollister criticizes the Federal Circuit opinion relying heavily on this

alleged admission. Hollister does not have the right to raise this as an issue at this late date. For,

> [i]t is well established that generally, absent a non-frivolous constitutional challenge, an issue cannot be raised for the first time in a judicial appeal.

Sanders v. United States Postal Service, 801 F.2d 1328, 1331-1332 (Fed. Cir. 1986).

Squibb will comment on this alleged admission. Hollister alleges that Squibb made an admission in, "Plaintiff's Response In Opposition to Defendant's Motion To Amend," a paper filed in the district court on April 4, 1987 before trial. Squibb's brief was filed in an attempt to prevent amendment of the answer and counterclaim after discovery had closed. Squibb, in it's response, outlined the dilatory tactics of Hollister in defining its defenses to infringement throughout discovery. The amendment to the answer and counterclaim raised for the first time the inequitable conduct defense. Inequitable conduct is a defense to infringement, and the basis for Hollister's allegations were contained in the prosecution history of the patent-in-suit, available to Hollister since July 17, 1984, a full three years before its motion to amend.

Second, Squibb attempted to show the court that the new allegation was not worth litigating because the mistake was not material and thus would not support inequitable conduct. The prosecution history showed that the examiner examined all of the claims, including several claims which were allowed after the examination and which were broader than the mislabeled claims 50 and 51, and therefore the error could not be material.

Squibb argued that there was a typographical error or inadvertence on the face of the document, without even having to consider the actual intent of Squibb as to which claims it wanted to file. Squibb noted that the use of "allowed" and "allowable" in the preliminary amendment was ambiguous. For example, the chart labeled "Number of Claims As Allowed" listed two dependent claims which were combined

into one claim in the continuation case. This new single claim could not have been previously allowed. There was also an indication that some dependent claims had been rewritten in independent from. A rewritten claim could not have been previously allowed. Squibb argued:

> On its face, there is an error but one can hardly conceive of an easier error to resolve. The document is ambiguous and the ambiguity is easily resolved by comparing the newly presented claims with the "allowable" and "allowed" claims 50 and 51 respectively in the parent case. That the error was both unintended and harmless is evidenced by the fact that the brand-new claims presented in the continuation application were allowed and that these claims are broader in scope than the claims being focused on by Defendant. The fact that the word "allowable" was intended is further evidenced by Applicant's statement that certain dependent claims had been *rewritten*. (original emphasis)

The evidence at trial was that the Squibb attorney intended that amended allowed claim 50 would be filed, not unamended claim 50. Hollister says this is inconsistent with the explanation of how the column was mislabeled in the opposition to the motion to amend. However, the proper reading of the brief is that the word "allowable" had to be intended when describing the dependent claims rewritten in independent form and the combined claim listed in the column because such claims, as written in the continuation, had never been passed on by the PTO and could not have had "allowed" status. Thus, there was ambiguity as to the status of all claims listed on the face of the document. Squibb argued that this ambiguity alone would have alerted the examiner to read all the claims and certainly would not have dissuaded him from performing his duty which required that he examine all the claims. Hollister's assertion of an admission is incorrect.

IV. The In Banc Ruling Of The Federal Circuit Clarifying The Existing Law Reversing The Decision Of The District Court Did Not Prejudice Hollister

The Federal Circuit clarified the law because some of its opinions had suggested that a finding of gross negligence compels a finding of intent to deceive where others had indicated that gross negligence alone did not mandate a finding of intent to deceive. This apparent inconsistency resulted from the fact that "gross negligence" had been used as a label for various patterns of conduct. However, as noted by the Federal Circuit, gross negligence is only definable in terms of a particular act or acts viewed in light of all the circumstances. Further, as stated by the Federal Circuit in its panel decision, pure error or ministerial mistakes "by definition result from inattention, and [are] less likely to result from the scienter involved in the more egregious acts of omission and commission which have been seen as reflecting the deceitful intent element of inequitable conduct in our cases." (H.P. 14a) As stated by the Federal Circuit,

> "Gross negligence" has been used as a label for various patterns of conduct. It is definable, however, only in terms of a particular act or acts viewed in light of all the circumstances. We adopt the view that a finding that particular conduct amounts to "gross negligence" does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive. See *Norton v. Curtiss* 433 F.2d 779, 167 U.S.P.Q. 532 (C.C.P.A. 1970).

(H.P. 16a)

For example, the Federal Circuit, in previous opinions when describing gross negligence which included actual withholding of highly material references with knowledge of the materiality, stated that the actor either knew or should have known the significance of his acts. This "known or

should have known standard" is therefore descriptive of such egregious acts. The problem, of course, is that the "known or should have known standard" also can be used to describe acts of simple negligence and was being used to the point that the Federal Circuit observed that "[t]he habit of charging inequitable conduct in almost ever major patent case has become an absolute plague." *Burlington Industries, Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). The Federal Circuit confirmed in its in banc decision that inequitable conduct requires materiality and intent. Its in banc decision reflects its prior decisions which recite, "[t]o be guilty of inequitable conduct, one must have intended to act inequitably." *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987). Therefore, the Federal Circuit did not overrule precedent but merely clarified and rendered guidance to lower courts in applying the inequitable conduct standard. As in this case, the Federal Circuit has simply made it clear that pure errors or ministerial errors without more cannot suffice for a fact-finding of sufficient culpability for a finding of intent to deceive. An inference of intent to deceive from gross negligence must be based on an assessment of all the evidence, including evidence indicative of good faith, and must indicate sufficient culpability to require a finding of intent to deceive. Thus, each particular set of facts viewed in light of the circumstances determine whether an intent to deceive is supported. (H.P. 10a)

This in banc ruling does not change the law or prejudice Hollister. Furthermore, as admitted by Hollister, the Federal Circuit concluded in light of all the evidence relating to the intent element of inequitable conduct, "that the evidence did not warrant *either* a finding of gross negligence or a finding of actual intent to deceive." (original emphasis) (H.P. 13) Thus, assuming that the in banc ruling changed the law and raised the standard to actual intent to deceive, Hollister has not been prejudiced. Again, the Federal Circuit found that under either standard Squibb was not guilty of inequitable conduct. (H.P. 9a)

Hollister further complains that it was prejudiced by the in banc ruling by the Federal Circuit because neither party requested such a ruling. (H.P. 13) Of course, as supported by this Court, the Federal Circuit may decide a case in banc upon its own initiative. It is not required that either party request such an in banc hearing. As sanctioned by this Court in *Textile Mills Security Corp. v. Commissioner*, 314 U.S. 326, 62 S.Ct. 272 (1941), a court of appeals may meet in banc. Furthermore, this Court has stated that the courts of appeals are given wide latitude in deciding when to hear a case in banc. In *Western Pac. R. Corp. v. Western Pac. R. Co.*, 345 U.S. 247, 73 S.Ct. 656 (1953), this Court approved a possible procedure wherein a court of appeals might choose to initiate a hearing in banc upon its own accord. Further, this Court in that same case found that a court of appeals meeting in banc can also limit the number of issues it hears.

28 U.S.C. § 46(c) of the Judicial Code expressly authorizes the Federal Circuit to meet in banc. Also, Rule 35 of the Federal Rules of Appellate Procedure provide that a majority of the circuit judges who are in regular active service may order that an appeal or other proceeding be heard or reheard by the court of appeals in banc. This is so whether a party suggests or requests that a hearing be in banc.

Hollister also complains that neither party was heard by the in banc court. (H.P. 13) However, neither party is guaranteed a right to additional briefing or oral argument in the case. Rule 34(a) of the Rules of Appellate Procedure provides that oral argument may be denied or not required where the court finds that the (1) appeal is frivolous, or (2) the depositive issue or set of issues has been recently authoritatively decided, or (3) the facts and legal arguments are adequately presented in the briefs and record and the decisional process would not be significantly aided by oral argument.

Hollister cites *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 91 S.Ct. 1434 (1971), for the proposition that it should be allowed to adduce additional evidence on the issue of actual intent under the in banc holding and have the court make additional findings and conclusions of law. (H.P. 26) The application of the holding in *Blonder-Tongue Laboratories, Inc.* is inappropriate under the facts of this case. In that case, the district court held that the patents were valid and infringed. The defendant appealed, and the court of appeals affirmed as to one patent. This Court granted certiorari.

This Court held that the patentee was estopped to assert validity of a patent that had been declared invalid in a prior law suit in federal court against a different defendant unless the patentee could demonstrate that he did not have a full and fair opportunity, procedurally, and substantively, and evidentially to litigate the validity of a patent in the prior suit. Hollister asserts that its right to due process of law was violated by the "change" in the law it argues resulted from the in banc decision citing *Blonder-Tongue*. First as pointed out above, the Federal Circuit did not change the law. Second, the Court in *Blonder-Tongue* stated that the case before it did not involve due process questions. 402 U.S. 329-30. The case simply overruled the holding in *Triplett v. Lowell*, 297 U.S. 638, 56 S.Ct. 645 (1936), which concerned the concept of mutuality of estoppel. Under the mutuality of estoppel doctrine, unless both parties in a second action are bound by a judgment in a previous action, neither party in the second action may use a prior judgment as determinative of an issue in the second trial. As a result of this doctrine, relitigation of the validity of a patent claim previously held invalid in a suit against a different defendant was not precluded. This Court specifically stated that the case depended on the considerations weighing for and against permitting a patent holder to sue on his patent after it has once been held invalid following opportunity for full and fair trial. Specifically, this Court limited its holding to the following:

> The patentee, plaintiff, must be permitted to demonstrate, if he can, that he did not have a fair opportunity procedurally, substantively, and evidentially to pursue his claim the first time.

402 U.S. at 333.

This Court found that because of the *Triplett* precedent the petitioner did not plead estoppel and respondents never had an opportunity to challenge the appropriateness of such a plea. Thus, the court remanded the case because of the partial overruling of *Triplett*. The court specifically found that the petitioner should be allowed to amend its pleadings in the district court and to assert a plea of estoppel. Further, the respondents must then be permitted to amend their pleadings, and to supplement the record with any evidence showing why estoppel should not be imposed in the case.

In the above case, the defendant would have pled estoppel but for the *Triplett* case law precedent. In the present action between Squibb and Hollister, Hollister did not forego a pleading of inequitable conduct because of case law which the Federal Circuit later clarified. Further, there is no evidence that Hollister has been prejudiced by the clarification of the law. Again, as admitted in its Petition for Writ of Certiorari, Hollister states that the Federal Circuit found that on either standard, gross negligence alone or intent to deceive, Squibb's actions did not constitute inequitable conduct. Furthermore, Hollister did not forego pleading inequitable conduct, did not forego submitting evidence on inequitable conduct, and was not prejudiced by any clarification of law. Thus, *Blonder-Tongue* is not applicable to the present action. If Hollister's argument is sanctioned by this Court, then every time an appellate court clarifies a statute or existing precedent or creates new precedent, the unsuccessful litigant will have the right to relitigate the entire case. The courts cannot sanction such a rule because it would significantly disrupt economical timely administration of the judicial process.

The record shows that Hollister submitted all of its evidence and argued deceitful intent as well as gross negligence. Hollister hired Mr. Sears, a former PTO staff attorney and Deputy solicitor, to study the patent and testify on the inequitable conduct issue. However, on the issue of intent Mr. Sears volunteered in direct examination:

> Now, frankly, I don't have enough knowledge of what went on here to say that anybody harbored true deceptive intent. You can't get that from the patent office records, and it doesn't come through to me from whatever Steve Davis has testified to.

Mr. Sears confirmed on cross-examination that he saw no evidence of actual deceptive intent on the part of Mr. Davis. Hollister's request to this Court to change the Federal Circuit's reversal order to a vacated order is a request to be able to present evidence directly opposite to the evidence presented at trial and is unconscionable. Such tactics are certainly not supported by any precedent of this Court.

CONCLUSION

It is clear from the Federal Circuit opinion that it did not simply substitute its judgment for that of the trial court. The Federal Circuit ruled after it had thoroughly reviewed the uncontested facts and the totality of the circumstances including the meticulous listing of factors in which the district court either drew improper inferences from or ignored and concluded:

> We are forced to the definite and firm conviction that a mistake has been committed, amounting to an abuse of discretion. The district court's finding of deceitful intent was clearly erroneous.

(H.P. 15a)

The decision of the Federal Circuit is properly based on Rule 52(a) of the Federal Rules of Civil Procedure and the rule set forth in *Anderson v. City of Bessemer City, N.C.*

Hollister was in no manner constrained in its presentation of evidence and arguments and the in banc ruling of the Federal Circuit can certainly not be said to have prejudiced Hollister. There is simply no grounds for Hollister to request that a Writ of Certiorari be granted. Accordingly, Squibb respectfully prays for denial of the Petition for a Writ of Certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in its cause number 88-1265.

Respectfully submitted,

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